

K090805 1/2

Page 5 - 1

# Innocoll

## Pharmaceuticals

Midlands Innovation and Research Centre  
Dublin Road,  
Athlone, Co. Westmeath, Ireland  
Tel: + 353 (0)90 6486834  
Fax: + 353 (0)90 6486835  
www.innocoll-pharma.com

FEB 1 6 2010

### 510(k) Summary

1. **Date Prepared:** September 1<sup>st</sup>, 2009
2. **Submitter** Innocoll Pharmaceuticals  
Midland Innovation and Research Centre  
Athlone  
Co. Westmeath  
Ireland.  
Tel: +353 (0) 9064 86834  
Fax: +353 (0) 9064 86835
- Submission Correspondent:** Aaron Wyse  
Director of Regulatory Affairs
3. **Proprietary Name:** Collagen Sponge
4. **Common Name:** Topical Wound Dressing
5. **Device Classification:** Product Code: KGN  
Classification Name: Dressing Wound Collagen  
Regulatory Class: Unclassified
6. **Statement of Substantial Equivalence:**

Collagen Sponge is substantially equivalent in materials of construction and intended use to CollaGUARD (K061746) and to Collieva (K081782) manufactured by Syntacoll GmbH.

**7. Intended Use**

Collagen sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

**8. Description**

Collagen Sponge is a collagen matrix sponge intended for topical use. The product is supplied sterile for single use only.

**9. Biocompatibility**

There are no new biocompatibility issues arising with the use of Collagen Sponge as the materials of construction and finished product material match that of CollaGUARD (K061746).

**10. Conclusion**

Collagen Sponge is substantially equivalent to the predicate devices delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

FEB 16 2010

Innocoll Pharmaceuticals  
% Mr. Aaron Wyse  
Director of Regulatory Affairs  
Midlands Innovation & Research Centre  
Dublin Road, Athlone, Co. Westmeath  
Ireland

Re: K092805  
Trade/Device Name: Collagen Sponge  
Regulatory Class: Unclassified  
Product Code: KGN  
Dated: January 27, 2010  
Received: February 2, 2010

Dear Mr. Wyse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 - Mr. Aaron Wyse

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K092805

## Statement of Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Collagen Sponge

Indications For Use:

### Indications:

Collagen Sponge may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

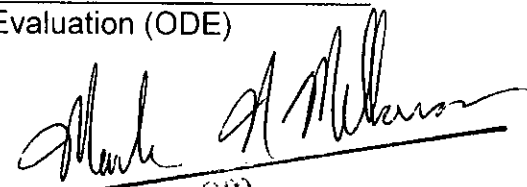
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number \_\_\_\_\_

K092805